

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

MEDTRONIC VASCULAR, INC., ET AL.,	§	
	§	
Plaintiffs	§	
	§	
v.	§	CIVIL ACTION NO. 2:06-CV-78
	§	
BOSTON SCIENTIFIC CORP., ET AL.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

I. BACKGROUND

In this case, plaintiffs Medtronic Vascular, Inc., Medtronic USA, Inc., Medtronic Inc., and Medtronic Vascular Galway (collectively, “Medtronic,” “Bard,”¹ or “plaintiffs”) obtained a jury verdict of infringement against defendants Boston Scientific Corp., Scimed Life Systems, Inc. and Boston Scientific Scimed, Inc. (collectively, “BSC” or “defendants”) with respect to United States Patent Nos. 6,190,358 (“the ‘358 patent”), 6,605,057 (“the ‘057 patent”), and 6,210,364 (“the ‘364 patent”). *See* Dkt. No. 213 (Jury Verdict). The ‘057 patent is a continuation of the ‘358 patent and are collectively referred to as “the Fitzmaurice patents.” The ‘364 patent is referred to as “the Anderson patent.”

The court conducted a bench trial on July 31, 2008, to resolve various defenses asserted by BSC. These defenses, asserted against both the Fitzmaurice and Anderson patents, are: (1) inequitable conduct, (2) indefiniteness, and (3) laches.

¹ Medtronic’s predecessor-in-interest, Bard, was the assignee of the patent applications that eventually issued as the patents-in-suit. Therefore, the actions of Bard during the pendency of these patent applications are attributable to Medtronic.

II. LEGAL STANDARDS

A. Inequitable Conduct

“A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006); *see also* 37 C.F.R. § 1.56(a) (“Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”).

The materiality of information withheld during prosecution may be judged by the “reasonable examiner” standard. *See id.* at 1316. That is, “[m]ateriality . . . embraces ‘any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.’” *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998) (citations omitted). Moreover, “[i]nformation concealed from the PTO may be material even though it would not invalidate the patent.” *Li Second Family LP v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000). “However, a withheld otherwise material [piece of information] is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner.” *Digital Control Inc.*, 437 F.3d at 1319 (Fed. Cir. 2006). “[T]he scope and content of prior art and what the prior art teaches are questions of fact.” *Id.*

“The intent element of the offense is . . . in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.” *Akron Polymer*, 148 F.3d at 1385. “However, inequitable conduct requires not intent to withhold, but

rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.” *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). In addition, “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).

“The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence.” *Digital Control*, 437 F.3d at 1313. “The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’” *Id.* (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

B. Indefiniteness

“Because claims delineate the patentee’s right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent.” *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). The Federal Circuit has held claims indefinite under 35 U.S.C. § 112, ¶ 2 for numerous circumstances. *See, e.g., Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007) (where a claim recites means-plus-function elements without disclosing corresponding structure in the specification); *Honeywell Int’l, Inc. v. Int’l Trade Comm’n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003) (where a claim

contains a numeric limitation without disclosing which of multiple known methods of measuring that number should be used); and *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (where a term is “completely dependent on a person’s subjective opinion”). “The common thread in all of these cases is that claims were held indefinite only where a person of ordinary skill in the art could not determine the bounds of the claims.” *Halliburton Energy Services*, 514 F.3d at 1249. However, disputes over testing methodology do not render a patent claim indefinite, but are rather a question of infringement. *See Marley Mouldings Ltd. v. Mikron Industries, Inc.*, 417 F.3d 1356, 1360 (Fed. Cir. 2005).

C. Laches

Laches “is an equitable defense which, if successful, bars recovery of damages for infringement which occurred prior to the filing of suit.” *See, e.g., A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1029-30 (Fed. Cir. 1992) (en banc). To successfully assert a laches defense, a defendant must prove:

1. the plaintiff delayed filing suit for an unreasonable and inexcusable length of time from the time the plaintiff knew or reasonably should have known of its claim against the defendant, and
2. the delay operated to the prejudice or injury of the defendant.

Costello v. United States, 365 U.S. 265, 282 (1961). “Material prejudice to adverse parties resulting from the plaintiff’s delay is essential to the laches defense.” *Aukerman*, 960 F.2d at 1033. Such prejudice may be either economic or evidentiary.

III. THE FITZMAURICE PATENTS

A. Inequitable Conduct

BSC argues that Bard, specifically its in-house patent agent James Crittenden, committed

inequitable conduct by failing to disclose various prior art catheters and did so with the intent to deceive the PTO. The court provides the following time line of events relevant to the prosecution of the Fitzmaurice patents and Crittenden's involvement:

1980	Crittenden joined Bard's R&D department.
1988-89	Crittenden, as head of R&D, first became aware of the Bard Sprint project.
1988-90	Bard conducted competitive testing on various catheters, and Crittenden's name appears on the distribution list of some of the generated reports. Dkt. No. 269 ("Crittenden Tr.") at 29:8-30:5.
1991	Crittenden left the R&D department and transferred to the Business Development group.
1994	Crittenden took the patent bar (he passed and was registered as a patent agent in 1995 at which time he moved into the Bard Legal Dept).
February 9 and 21, 1995	Sweedler, attorney at Darby & Darby, and his colleague speak with Crittenden concerning the PCT application related to the Fitzmaurice patents. Defts.' Opening Br., Ex. 28 at DARBY000003.
February 24, 1995	Bard files the original PCT application (PCT/US95/02783) from which the Fitzmaurice patents descend. <i>Id.</i> , Ex. 69.
January 24, 1996	Strong, Bard's patent manager, sends Crittenden a "confidential memorandum regarding patent issues relating to catheter" Defts.' Opening Br., Ex. 27 ("Log") No. 378.
June 21, 1996	Strong sends a "confidential memorandum regarding patentability of device," copying Crittenden and Fitzmaurice. Log No. 391.
May 20, 1997	Bard files a continuation application (No. 08/859,654), which would ultimately issue as the '358 patent. Defts.' Opening Br., Ex. 70.

January 28, 1998	Sweedler corresponds with Crittenden. Log. No. 498
June 3, 1998	The PTO rejects all of the pending claims as anticipated by U.S. Patent No. 5,695,468 (“Lafontaine”).
June 19, 1998	Sweedler’s colleague at Darby & Darby, Bab, sends Crittenden a “confidential attorney-client communication regarding office action.” Log No. 512.
June 30, 1998	Bab sends Crittenden another “confidential attorney-client communication regarding office action.” Log No. 513.
July 13, 1998	Bab sends Crittenden a “confidential attorney-client communication regarding draft amendment.” Log No. 516.
July 13-29, 1998	Bab speaks with Crittenden three times concerning the Fitzmaurice patent application. Defs.’ Opening Br., Ex. 28 at DARBY000025.
July 25, 1998	Crittenden sends Fitzmaurice a “confidential attorney-client communication regarding changes to patent application for catheter.” Log No. 520.
Aug. 21 - Sept. 4, 1998	Bab and Crittenden exchange four communications regarding “amendments” and “office actions.” Log Nos. 528, 529, 530 and 532.
September 8, 1998	Bard (through Darby & Darby) files an amendment and a written response in an attempt to overcome LaFontaine. Defs. Opening Br., Ex. 71.
November 3, 1998	The PTO again rejects the independent claims as being anticipated by LaFontaine.
January 4, 1999	Crittenden sends Sweedler a “confidential attorney-client communication regarding office action.” Log No. 565.
Jan. 8 - Feb. 8, 1999	Medtronic and its attorneys at Darby & Darby and Sterne Kessler exchange ten communications, either authored or received by Crittenden, relating to the application file and Medtronic’s response to the examiner’s office action. Log Nos. 577, 578, 579, 580, 582, 583, 584, 585, 589 and 590.

February 3, 1999	Teresa Medler of Sterne Kessler speaks with Crittenden about the Fitzmaurice patent application. Defts.' Opening Br., Ex. 29 at SKFG000273.
February 8, 1999	David Cornwell of Sterne Kessler appeared for Medtronic, proposing an amendment to overcome the rejection over LaFontaine. Defts.' Opening Br., Ex. 72.
March 1-26, 1999	Medtronic and Sterne Kessler exchange five more communications, either authored or received by Crittenden, relating to "issues relating to patentability," the "patent filing," "patent application status," and "communications with Examiner." Log Nos. 601, 602, 603, 604, 607 and 610.
March 31, 1999	Medtronic appoints Crittenden and others as new attorneys of record, "with full power of substitution, association, and revocation, to prosecute said application and to transact all business in the United States Patent and Trademark Office connected therewith." Defts.' Opening Br., Ex. 73.
April 7-12, 1999	Medtronic and Sterne Kessler exchange four more communications, either authored or received by Crittenden, relating to "interaction with patent examiner" and "issues related to patentability." Log Nos. 612, 613, 614 and 615.
May 10-13, 1999	Crittenden corresponds with Fitzmaurice and Catherine Maresh, a Medtronic in-house patent lawyer, concerning amendments and issues of inventorship. Log Nos. 617 and 618.
May 17, 1999	Crittenden sends Fitzmaurice three communications relating to patent issues and patent prosecution. Log Nos. 621, 622 and 623.
June 1999	Crittenden suffers a grand mal seizure. ²
July 9, 1999	The examiner rejects all of the independent claims as being

² According to Crittenden, this seizure has affected his memory of the events during the prosecution of these patents. This condition was not revealed by the plaintiffs to the defendant or this court until the day of the bench trial. Crittenden Tr. 59:21-60:18. In the course of four depositions involving the Fitzmaurice patents, Crittenden never mentioned any memory issues. Crittenden Tr. at 59:25-60:23.

anticipated by U.S. Patent No. 5,545,134 (“Hilaire”).

September 1999	Crittenden returned to work part-time.
September 27, 1999	Crittenden attends a meeting at Sterne Kessler concerning the Fitzmaurice patent application. Defts.’ Opening Br., Ex. 30 at SKGF000294.
Oct. 4 - Nov. 9, 1999	Crittenden takes part in six more phone conferences with attorneys at Sterne Kessler concerning the Fitzmaurice patent application. Defts.’ Opening Br., Ex. 30 at SKFG000296 and SKFG000302. During the same period, Crittenden authors or receives at least five communications with Sterne Kessler and/or the inventors concerning the Fitzmaurice application. Defts.’ Opening Br., Ex. 29 at Nos. 38 39, 47, 50 and 51.
Dec. 7 - Jan. 10, 1999	Crittenden receives correspondence from Sterne Kessler relating to “disclosures responsibilities in connection with patent process” and “filings in connection with patent application for catheter.” Log Nos. 687 and 692. During the same period, Crittenden sends three communications to Sterne Kessler concerning filings with the PTO. <i>Id.</i> at Nos. 32, 33 and 35.
January 10, 2000	Medtronic responds to the examiner’s office action, submitting the inventors’ declaration that they reduced their invention to practice earlier than the priority date of Hilaire.
March 20, 2000	The examiner allows the independent claims. Defts.’ Opening Br., Ex. 74.
September 19, 2000	The PTO issued its Notice of Allowance. Defts.’ Opening Br., Ex. 32.
February 19, 2001	The continuation application leading to U.S. Patent No. 6,605,057 was filed.
February 20, 2001	The ‘358 Patent issued.
August 12, 2003	The ‘057 Patent issued.

Medtronic argues that Crittenden was not substantively involved in the prosecution of the

Fitzmaurice patents and therefore did not owe a duty of candor to the PTO. The court rejects this argument. During his testimony, Crittenden acknowledged responsibility in the prosecution of the Fitzmaurice patents:

Q. You were one of the people responsible for turning over prior art to give to the patent office, right?

A. Yes.

Crittenden Tr. at 67:23-68:1. More telling, however, is the extensive communications between Crittenden and the law firms retained by Bard to prosecute these patents, as detailed in the timeline above. This court will not speculate as to the substance of these communications.³ From the timing and frequency of these communications, however, the court finds that Crittenden was an individual who was substantially involved in the prosecution of the Fitzmaurice patents. Crittenden does not deny that he was substantively involved:

Q. Now, are you denying you didn't, or is this just maybe something that because of lapse of time or your surgery you've forgotten about?

A. I think it's the latter. Seeing all these documents, clearly my name is on a lot of documents relating to this case. I just have no recollection of -- of any activity on this case.

Crittenden Tr. at 25:8-14.

Having found the Crittenden was substantially involved, it follows that Crittenden owed a duty of candor to the PTO in the prosecution of the Fitzmaurice patents. As part of his duty of candor, he had the duty to submit known prior art which a reasonable examiner would find material to the prosecution of these patents. Of the prior art references that BSC argues should have been

³ Though Crittenden reviewed the privilege log, he did not review the documents themselves. See Crittenden Tr. 62:15-63:19.

disclosed to the PTO, the court focuses on Bard's own product—the Sprint catheter. It is indisputable that Crittenden had knowledge of the Sprint catheter:

Q. You were certainly aware within the group, the patent group, the folks that filed the Fitzmaurice application, of the Sprint catheter, right?

A. Yes.

Q. The patent office wasn't aware of it, at least you didn't make them aware of it?

A. That's correct.

Crittenden Tr. at 75:20-76:1. In fact, Crittenden was the head of Bard's Research and Development department at the time the Sprint catheter was being designed. Medtronic does not appear to dispute Crittenden's knowledge of the existence of the Sprint catheter; rather, Medtronic argues that "Crittenden had no reason to believe that the Sprint had a tapered guide wire lumen, substantially prevented blood entry, or allowed the guide wire to be coated with anticoagulant." Pls.' Post-Bench Trial Br. at 8. In other words, Medtronic would have this court determine the materiality of prior art based on Crittenden's subjective belief as to the scope of the invention. This court declines to do so. The Federal Circuit precedent directs this court to determine what would have been material to a reasonable examiner. In other words, "[i]nformation is material for the purposes of an inequitable conduct determination if a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application." *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314 (Fed. Cir. 2006) (internal citation omitted).

This court finds that the Bard Sprint catheter was material and not cumulative prior art. In response to the examiner's second rejection on § 102 grounds based on Lafontaine, the applicants amended the pending claims. This amendment explicitly recited that the distal portion was "of a first

length” and the proximal portion was “of a second length longer than the first length.” Defts.’ Opening Br., Ex. 72 at MEDBSC00002652. This additional claim language, according to the applicants, “results in a structural difference between the claimed invention and the Lafontaine patent.” *Id.* at MEDBSC00002654.

The Bard Sprint, however, had a reduction in diameter in its distal portion. *See, e.g.*, Crittenden Tr. at 72:18-24; *see also* Dkt. No. 227 at 85:1-6 (trial testimony of Jon McIntyre). Therefore, taking the applicants’ view of Lafontaine, the court finds that the Bard Sprint was not cumulative. In fact, the applicants could not have made the amendments and related arguments they did in response to the examiner’s second rejection in light of Lafontaine had the Bard Sprint been before the examiner. Furthermore, again assuming the applicants’ statements made during the course of prosecution were correct, the applicants argued that Lafontaine was not even prior art to the Fitzmaurice applications.⁴ For these reasons, the court finds that the Bard Sprint catheter was highly material prior art.

Having found materiality, the court turns to whether Crittenden possessed the requisite intent to deceive the patent office. As an initial matter, “a high degree of materiality, coupled with evidence that the applicant should have known of that materiality, creates a strong inference of an intent to deceive.” *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1376 (Fed. Cir. 2007).

The only witness called at the bench trial was Crittenden. Through his testimony, Medtronic argues that Crittenden, in good faith, did not disclose the Bard Sprint because Crittenden did not

⁴ The examiner never addressed the substance of the applicants’ arguments with respect to the second rejection in light of Lafontaine. Rather the examiner stated that the arguments were moot in light of the examiner’s new rejection. Defts.’ Opening Br., Ex. 10 at 4.

believe that it was material.⁵ This court does not find Crittenden's testimony credible.⁶

Crittenden dogmatically insisted in his testimony before this court that the invention described in the Fitzmaurice patent was the tapered tip. *See, e.g.*, Crittenden Tr. at 19:18-20:3. This belief came from his review of the internal Bard invention disclosure statement, a document never disclosed to the PTO. *See, e.g., id.* at 68:5-25. Crittenden further testified that he never read the claims that were submitted in the patent application to determine the scope of the invention. *Id.* To the extent this testimony is even true, Crittenden, as a registered patent agent, could not faithfully discharge his duty of candor by remaining ignorant to the claims themselves. Medtronic's arguments to the contrary turn a fundamental principle of patent law on its head. It is the claims that define the scope of the invention, and it is the claims that determine what prior art would be material to the prosecution of a patent application. By relying on only the internal invention disclosure statement prepared by the inventors, Crittenden, at best, chose to remain deliberately ignorant as to the scope of the invention. In failing to read the claims, Crittenden could not know what was material prior art to the prosecution of the Fitzmaurice application.

The examiner, however, solved Crittenden's selective ignorance of what was material art to the examiner when he rejected the pending claims as being anticipated by U.S. Patent No. 5,695,468 ("Lafontaine"). The examiner stated:

⁵ This court is left to speculate as to Crittenden's reasoning, if any, at the time the prosecution was ongoing. Crittenden neither confirmed or denied considering whether to disclose the Bard Sprint during the pendency of the Fitzmaurice application. Crittenden Tr. at 75:13-76:1.

⁶ The court notes that Crittenden was able to recall many details of events and circumstances around the same time as the Fitzmaurice patent. Yet, in the face of a privilege log documenting dozens of communications from or to Crittenden, he was unable (or unwilling) to directly answer broad and general questions.

Lafontaine et al. discloses a balloon catheter comprising a shaft, a guidewire tube having a lumen where the distal portion has a first diameter and the proximal portion has a second diameter larger than the first diameter, a fluid channel, and a balloon.

June 3, 1998 Office Action at 3. Then pending claim 1 recited:

the guide wire lumen has a distal portion of a first diameter and a proximal portion of a second diameter larger than the first diameter, the length of the distal portion and the first diameter being select such that when a guide wire is within the guide wire lumen, blood is substantially prevented from entering the proximal portion. . .

See September 3, 1998 Response to the June 3, 1998 Office Action at 4. Faced with this rejection and the indisputable statement of what the examiner believed was material art, Crittenden still concealed Bard's own Sprint catheter.

Medtronic argues that "[t]here is no evidence that anything that occurred during the prosecution of [the Fitzmaurice patents] . . . triggered in Mr. Crittenden's mind the affirmative duty to search the annals of Bard's files for the references that BSC now asserts were withheld with deceptive intent." Pls.' Post-Bench Trial Br. at 15. The court strongly disagrees. The examiner's rejection based on Lafontaine conclusively identified what features in the prior art the examiner believed to be material. This rejection put Crittenden on notice that a catheter with "a lumen where the distal portion has a first diameter and the proximal portion has a second diameter larger than the first diameter" was in fact material. At the very minimum, this should have triggered Crittenden to review the pending claims that the examiner rejected, and disclose art that he knew or should have known to be material. Instead, Crittenden continued to cultivate his ignorance.

This court is well aware that "[g]ross negligence is not sufficient" to support a finding of intent to deceive the patent office. *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1360 (Fed. Cir. 2008) (citing *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed.

Cir. 1988) (en banc)). The evidence presented by BSC to this court, however, exceeds that of gross negligence. Crittenden, as a patent agent who was substantially involved in the prosecution of these patents, cultivated deliberate ignorance of what a reasonable examiner would consider material art. To hold otherwise would condone, and in fact encourage, those with a duty of candor to act in such a manner. Therefore, this court finds that Crittenden acted with the intent to deceive the patent office by failing to disclose the Bard Sprint catheter.

This court is mindful of the recent Federal Circuit decision addressing the intent prong of inequitable conduct. *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., et al.*, Slip Op. 2007-1448 (Fed. Cir. August 25, 2008). The Federal Circuit held that an accused infringer alleging intent to deceive “cannot carry its burden simply because [the plaintiff] failed to prove a credible alternative explanation.” *Id.* at 16 (citing *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1340 (Fed. Cir. 2006)). Additionally, the Federal Circuit found that the accused infringer had a “major gap” in its proof of intent. *Id.* In the present case, BSC has no gaps and has discharged its burden to prove intent to deceive. Though there may not be direct evidence to support intent, which is rarely if ever available, this court finds that the circumstantial evidence leads this court to find that the single most reasonable inference to be drawn is that Crittenden intended to deceive the patent office. *See, e.g., id.* at 13; *see also Labounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (“[d]irect proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances.”) (citations omitted).

Having found that the threshold levels of materiality and intent are satisfied, the court balances the high level of materiality with the extant level of deceptive intent, and concludes that Crittenden committed inequitable conduct. The court therefore concludes that the ‘057 patent and

‘358 patents are unenforceable.

B. Indefiniteness and Laches

Because the court has found that the Fitzmaurice patents are unenforceable due to inequitable conduct committed during their prosecution, the court does not need to reach the issues of indefiniteness or laches with respect to these patents.

IV. THE ANDERSON PATENTS

A. Inequitable Conduct

BSC raises three separate grounds which it argues support a finding of inequitable conduct with respect to the Anderson patent:

1. Bard intentionally concealed material information concerning its own balloons, which BSC alleges possess all three of the Anderson characteristics. The specific devices are Bard’s Profile Plus, Simplus PE/t, Probe III, and Force;
2. Bard concealed and misrepresented information to the PTO regarding the ratio of hard and soft segments; and
3. Bard submitted false and misleading data, the graph (Defts.’ Opening Br., Ex. 48 at MEDBSC00003974), to the PTO regarding the prior art Gahara and Levy patent.

Turning to BSC’s argument regarding the failure to submit specific Bard balloons (namely, Profile Plus, Simplus PE/t, Probe III, and Force) to the examiner during the prosecution of the Anderson patents. Each of these balloons were made from PET, which is not a block copolymer. The asserted claims of the Anderson patents are directed to a block copolymer.

Medtronic argues that the fact that these balloons were not made from copolymers means that a reasonable examiner would not have found them to be material to the prosecution of the patents.

The examiner had before him U.S Patent 4,950,239 (“Gahara”), which did disclose a block copolymer. Medtronic argues the “fact that none of [the balloons identified by BSC] were made from a block copolymer is a very significant difference that dispels BSC’s materiality assertion.” Pls.’ Resp. Br. at 31 (citing *Halliburton*, 925 F.2d at 1441).

With respect to the Bard prior art balloons, BSC alleges that Bard knew, at the time of prosecuting the Anderson patents, that: (1) “all of its PET balloons had an elastic stress response value of less than 5.00” Defts.’ Opening Br. at 39; (2) “all of its PET balloons had a wall tensile strength of at least 14,000 psi” *Id.* at 40; and (3) “many of its PET balloons had a distensibility of ‘between about 5% and about 20%.’” *Id.* During the bench trial, BSC was able to elicit testimony from Crittenden regarding the knowledge within Bard of properties of the PET balloons. Crittenden Tr. at 78:17-80:10.

The court finds that this issue turns on the fact that the Anderson patents claim a block copolymer, which PET is not. Further, the examiner had before him U.S. Patent RE 32,983 (“Levy”), a patent directed to the manufacture of PET balloons. Therefore, the court finds that the prior Bard balloons were not material and/or cumulative of references already before the examiner.

BSC next argues that the patentee misrepresented that ratio of hard to soft segments.⁷ A 1993 internal memo written by one of the named inventors, Jay Jandris, indicated that Bard was aware that Pellethane 2363-75D, a material used in the Anderson patents, had a “high ratio of hard segment[s] to soft segment[s].” Defts.’ Opening Br., Ex. 58 at MEDBSC00003502. BSC argues that this is in stark contrast to the applicants’ statements made in the October 1, 1996 response to an examiner’s rejection in light of Gahara. In arguing around Gahara, the applicant stated that the applicants’

⁷ BSC did not advance this argument in its post-bench trial brief.

invention had a “considerably different” and “substantially lower” ratio of hard to soft segments. Defts.’s Opening Br., Ex. 48 at MEDBSC00003949. BSC notes that the examiner “apparently withdrew the inherency rejection” based on the representation made by Bookstein, Bard’s patent counsel. Defts.’ Opening Br. at 43.

The court acknowledges that this particular aspect of the Anderson prosecution raises a question of whether the applicants and their representatives faithfully discharged their duty of candor. The court finds, however, that the evidence presented by BSC with respect to this argument does not satisfy the clear and convincing burden required to prove inequitable conduct. Specifically, BSC presented insufficient evidence to support a finding of intent to deceive the patent office.

BSC’s final argument relates to Bookstein’s characterizations of the distensibility taught in the prior art. Defts.’ Opening Br., Ex. 48 at MEDBSC00003972-74. In the February 27, 1997 response, Bookstein attached a graph that BSC contends would lead the examiner to believe that actual measurements or testing was performed to generate the plotted data. Mr. Bookstein admits that he generated this chart solely from the teachings of the prior art. According to Medtronic, the graph submitted to the PTO was discussed in an interview with the examiner.

While the court finds that the graph unnecessarily implies that testing was conducted, this does not rise to a clear and convincing level of intent to deceive the PTO—especially in light of the testimony that this graph was first sketched in the presence of the examiner during an interview.

Finding that BSC has failed to meet its burden with respect to each argument, the court finds that the Anderson patents were not procured through inequitable conduct and are therefore not rendered unenforceable.

B. Indefiniteness

BSC argues that the Anderson patent is indefinite “[b]ecause the measurement method used can determine whether a given balloon product falls within the claims, and because the patent provides no guidance as to the methods to be used, it is impossible for a competitor to ascertain whether its products infringe the asserted claims.” BSC Opening Br. at 2. This argument focuses on the terms “elastic stress response” and “distensibility.”

BSC’s legal argument rests primarily on the Federal Circuit’s opinion in *Honeywell International, Inc. v. International Trade Comm’n*, 341 F.3d 1332 (Fed. Cir. 2003). Medtronic’s argument rests primarily on the Federal Circuit’s opinion in *Marley Mouldings Ltd. v. Mikron Indus., Inc.*, 417 F.3d 1356 (Fed. Cir. 2005).

The court concludes that *Marley Mouldings* controls the present dispute. The manner in which the experts conducted these tests to obtain data to calculate the elastic stress response and distensibility of the accused devices is an issue of infringement. This issue was extensively argued to the jury. The jury apparently decided to credit the testing methodology used by Medtronic’s expert, Mr. Sheehan. This court will not disturb that finding.

C. Laches

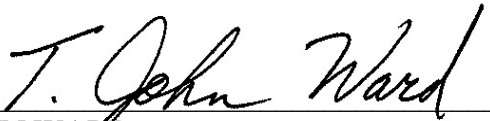
BSC argues that laches applies here because (1) Medtronic delayed filing suit for 5 years after raising the Anderson patent with BSC in 2001; and (2) the delay resulted in both economic and evidentiary prejudice to BSC. As a result, BSC asks the Court to limit any award of damages to the period after March 1, 2006. After carefully considering the arguments, the court is not persuaded that BSC has successfully carried its burden in showing that it has suffered either economic or evidentiary prejudice.

V. CONCLUSION

The court finds that the Fitzmaurice patents, U.S. Patent Nos. 6,190,358 and 6,605,057, are unenforceable due to inequitable conduct committed during their prosecution; however, BSC has failed to meet its burden in showing that the Anderson patents are unenforceable due to inequitable conduct. Given the court's finding of unenforceability as to the Fitzmaurice patents, the court does not need to reach the remaining issues raised by BSC with respect to those patents. With respect to BSC's indefiniteness and laches defenses to the Anderson patents, the court finds that BSC has failed to meet its burden as to both.

IT IS SO ORDERED.

SIGNED this 28th day of August, 2008.



T. JOHN WARD
UNITED STATES DISTRICT JUDGE